



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 10 1998 8 32 8 '98 NOV 18 P2:12

Mr. John Morley
President
Natural Factors Nutritional Products, Inc.
1420 80th Street, S.W.
Suite B
Everett, Washington 98203

Dear Mr. Morley:

This is in response to your letters of October 29, 1998 and November 2, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions state that Natural Factors Nutritional Products, Inc. is making the following claims, among others, for the products:

Menopause Formula

"...improving menopausal symptoms"

Zinc Citrate 15 mg, Zinc Citrate 50 mg, Zinc Chelate 25 mg

"...widely used for prostate problems"

Cranberry Juice Extract 18:1

"...inhibit bacteria from attaching themselves to the urinary tract and bladder..."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate a disease, namely, disturbances associated with menopause, prostate disorders, and urinary and bladder infections caused by pathogenic microorganisms. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET233

Page 2 - Mr. John Morley

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Seattle District Office, Office of Compliance, HFR-PA340

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Dorsey)
r/d:HFS-456:RMoore:11/10/98
f/t:HFS-456:rjm:11/10/98:docname:62166.adv:disc33



Natural Factors Nutritional Products Inc.

October 29, 1998

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

11/9/98

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Zinc Chelate 25mg

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
3655 Bonneville Pl.
Burnaby, BC
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.
1420 80th St. SW, Suite B
Everett, WA 98203

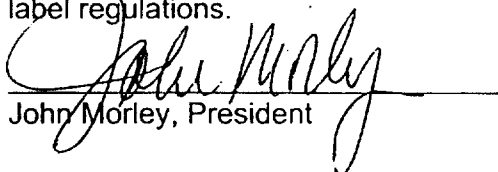
Text of the side panel: Natural Factors Zinc Chelate contains 25mg of this important trace mineral. Zinc supports our body's natural defenses and is essential for healthy skin. It is needed for many hormones and supports a healthy reproductive system, hence it is widely used for prostate problems.* Zinc is necessary for our sense of smell, taste and vision. Zinc Hydrolyzed Vegetable Protein chelates are made from rice to promote absorption.

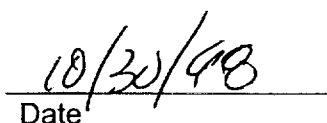
Text on PDP: Support for the body's defenses and reproductive system*

Name of dietary ingredient that is the subject of statement: Zinc Chelate

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.


John Morley, President


Date



Natural Factors Nutritional Products Inc.

October 29, 1998

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

11/9/98

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Zinc Citrate 50mg

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
3655 Bonneville Pl.
Burnaby, BC
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.
1420 80th St. SW, Suite B
Everett, WA 98203

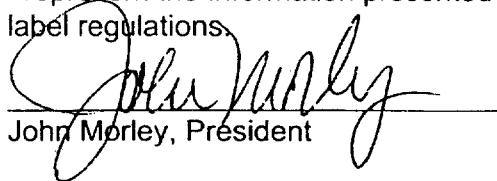
Text of the side panel: Natural Factors Zinc Citrate tablets contain 50mg of this important trace mineral. Zinc supports our body's natural defenses and is essential for healthy skin. It is needed for many hormones and supports a healthy reproductive system, hence it is widely used for prostate problems.* Zinc is necessary for our sense of smell, taste and vision. Zinc Citrate is an excellent form of zinc as citrates are extremely well absorbed and well-tolerated by the body.

Text on PDP: Support for the body's defenses and reproductive system*

Name of dietary ingredient that is the subject of statement: Zinc citrate

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.


John Morley, President

10/30/98
Date



Natural Factors Nutritional Products Inc.

October 29, 1998

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

11/9/98

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Zinc Citrate 15mg

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
3655 Bonneville Pl.
Burnaby, BC
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.
1420 80th St. SW, Suite B
Everett, WA 98203

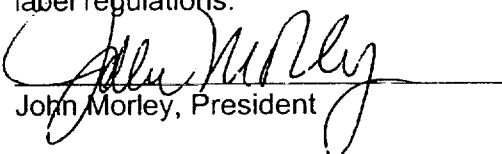
Text of the side panel: Natural Factors Zinc Citrate tablets contain 15mg of this important trace mineral. Zinc supports our body's natural defenses and is essential for healthy skin. It is needed for many hormones and supports a healthy reproductive system, hence it is widely used for prostate problems.* Zinc is necessary for our sense of smell, taste and vision. Zinc Citrate is an excellent form of zinc as citrates are extremely well absorbed and well-tolerated by the body.

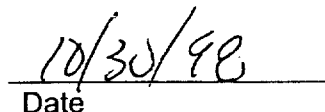
Text on PDP: Support for the body's defenses and reproductive system*

Name of dietary ingredient that is the subject of statement: Zinc citrate

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.


John Morley, President


Date



Natural Factors Nutritional Products Inc.

October 29, 1998

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

11/9/98

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Menopause Formula

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
3655 Bonneville Pl.
Burnaby, BC
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.
1420 80th St. SW, Suite B
Everett, WA 98203

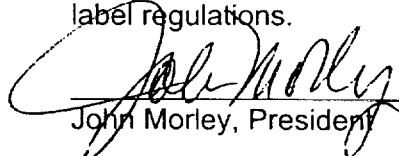
Text of the side panel: Natural Factors Menopause Formula is a special formulation containing a special blend of standardized botanicals recognized for their healthy attributes and naturally occurring phytoestrogens. This unique formula contains Black Cohosh, renowned for improving menopausal symptoms. Bring your body back to a natural balance gently and safely during mid-life changes.*

Text on PDP: Herbal Support for Menopause*

Name of dietary ingredient that is the subject of statement: Black Cohosh

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.


John Morley, President

10/30/98
Date



Natural Factors Nutritional Products Inc.

NOV 10 1998

November 2, 1998

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

RECEIVED
11/9/98

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Cranberry Juice Extract 18:1

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
3655 Bonneville Pl.
Burnaby, BC
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.
1420 80th St. SW, Suite B
Everett, WA 98203

Text of the side panel: Natural Factors Cranberry Juice extract is a concentrated, standardized extract derived from the juice of unsweetened cranberries. Cranberry Juice contains factors that inhibit bacteria from attaching themselves to the urinary tract and bladder, important for urinary health. Cranberry juice supports a healthy urinary tract in men as well as women.*

Text on PDP: Maintains a healthy Urinary Tract*

Name of dietary ingredient that is the subject of statement: Cranberry Juice Extract

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.


John Morley, President


Date

1420 80th Street S.W., Suite B.
Everett, WA, USA 98203
PHONE (425) 513-8800
FAX (425) 348-9050

Also see docket 975-0163

62204